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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,478	07/11/2007	Timothy Crowder	9336.14	1216
98819	7590	08/04/2011		
Myers Bigel Sibley & Sajovec, P.A. PO Box 37428 Raleigh, NC 27627			EXAMINER LOUIS, LATOYA	
			ART UNIT 3771	PAPER NUMBER
			NOTIFICATION DATE 08/04/2011	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/595,478	Applicant(s) CROWDER ET AL.	
	Examiner LaToya M. Louis	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-15,17,18,20-26,32,62 and 66-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-15,17,18,20-26,32,62 and 66-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This office action is responsive to the amendment filed 12/6/2010. As directed by the amendment, claims 1, 4, 18, 26, 32, 62, 66, 68, and 70 have been amended, claims 2, 3, 16, 19, 27-31, 33-61, and 63-65 have been cancelled, and claim 72 has been added. Thus claims 1, 4-15, 17, 18, 20-26, 32, 62, and 66-71 are currently pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 4, the limitation “the flexible floor layer” lacks antecedent basis.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 12, 25, 32, 62 and 68-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snow (2002/0134382 A1) in view of Ede (7,588,030).

Regarding claims 1, 32, and 62 Snow teaches the apparatus and method wherein in figs. 1a and 1e a multi-dose blister package having a plurality of blisters thereon and adapted for use in an inhaler, comprising: a polymeric frame member (i.e. 108) having opposing top and bottom surfaces with a plurality of spaced apart gap spaces (148,152), a respective gap space configured to define at least a portion of a sidewall of a respective blister, wherein the frame gap spaces are circumferentially spaced apart through- apertures arranged in two substantially concentric rows ([0070]); and a floor comprising a flexible material ([0077] and [0086] discloses semi-rigid material which is more rigid than foil but still relatively flexible [0131]) directly attached to the bottom surface of the frame member so that the floor extends under each gap space to define a bottom of each blister; and a ceiling (104) comprising a flexible material ([0063]) directly attached to the top surface of the frame member so that the ceiling extends above each gap space to define a top of each blister, wherein each blister holds dry powder medicament (216) and, when sealed, is devoid of any movable internal component therein such that the dry powder can

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directly contacts the frame sidewalls of a respective blister (fig. 4a), and wherein the blister package has an annular shape with an open center (136).

Snow teaches a frame (108) but does not specifically disclose that the frame is at least 10 times thicker than the thickness of the floor and the ceiling. However, Ede teaches in figs. 1 and 2 a frame (10) having a thickness 10 times greater than the floor (14) or the ceiling (12). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the frame of Snow with a thicker frame as taught by Ede to allow for larger numbers of doses to be contained as disclosed by Ede in col. 3 lines 36-40.

Regarding claims 25, 68, and 70, Snow discloses that the frame member apertures are inclined 30-45 degrees ([0150] discloses that the lancet is shaped to enter the blister and extends 30-45 degrees) and wherein the floor is planar (as shown in figs. 1c, 1d, and 2a, the bottom of each blister as floor is planar. Alternatively, if the package was placed upside down, planar surface 104 would act as the floor).

Regarding claims 12 and 69, Snow teaches an inhaler- mounting member (fig. 5A) to the frame member so that the mounting member resides upward through a center space of the annular ceiling, floor and frame ([0119]) with a rotatable gear (i.e. 314) having circumferentially spaced apart gear teeth ([0073]), the gear extending through the open center and attached to the frame member so that the blister package rotates with the gear. ([0073] and [0119]).

7. Claims 1, 4-11, 13-18, 20-24, 26, 32, 62, 66, 67, 69, 71, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickey et al. (WO 01/68169) in view of Ede.

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Regarding claims 1, 32, 62 and 69, Hickey teaches from figs. 1 and 3A the apparatus and method including a multi-dose blister package having a plurality of blisters (40) thereon and adapted for use in an inhaler, comprising: a floor (the combination of barrier 35, pads 25u,25b and substrate layer 28 as floor. Alternatively, sealant layer 45 as floor, depending on the orientation of the device) comprising a flexible material (page 19 lines 29-31) and the floor extends under each blister (40) to define a bottom of each blister wherein the blisters are circumferentially spaced apart (Fig. 6B) arranged in two substantially concentric rows (As shown in figs. 6A and 6B, the blisters are arranged in concentric rows); a ceiling (sealant layer 45 as ceiling. Alternatively, the combination of barrier 35, pads 25u,25b and substrate layer 28 as ceiling depending on the orientation of the device) comprising a flexible material (page 21 line 25 discloses that the ceiling 45 can be torn open) and the ceiling extends above each blister to define a top of each blister wherein each blister holds dry powder medicament (30) and when sealed is devoid of any movable component such that dry powder is able to contact this sides of a respective blister (as shown, in fig. 3a, the powder 30 is able to contact the sides of the blister) and wherein the blister package has an annular shape with an open center (20o).

Hickey teaches in figs. 3A and 6B circumferentially spaced blisters (40) filled with dry powder (30) directly contacting the sides of each blister and an inhaler mounting member (10) attached to the blister package and residing upward through a center space (20o) of the blister but does not teach a frame member having opposing top and bottom surfaces with a plurality of spaced apart gap spaces, a respective gap space configured to define at least a portion of a sidewall of a respective blister wherein the gap spaces are through apertures, and wherein a floor is directly attached to the bottom of the frame member and a ceiling is directly attached to a top

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of the frame member. However, Ede teaches in figs. 1d, 5, and 8 a rigid polymeric frame member (10) (col. 6 lines 22-23) having opposing top and bottom surfaces with a plurality of spaced apart gap spaces (18), a respective gap space configured to define at least a portion of a sidewall (16) of a respective blister (20), a floor (60) directly attached to the bottom of the frame member, a ceiling (59) directly attached to the top surface of the frame member so that the ceiling extends above each gap space to define a top of each blister so that the inhaler mounting member resides upward through a center space of the annular ceiling, floor, and frame, the frame member (10) having a thickness that is at least 10 times greater than the thickness of the floor (i.e. 14) and ceiling (i.e. 12). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the blister pack of Hickey with the frame as taught by Ede to allow for larger numbers of doses to be contained as taught by Ede in col. 3 lines 36-40.

Regarding claim 4, Hickey teaches from figs. 3, 4, 7, and 8 a bolus quantity of dry powder (30) disposed in respective blisters and that the combination of barrier 35, pads 25u, 25b and substrate layer 28 as floor or sealant layer 45 as floor, depending on the orientation of the device are both substantially planar and the modified Hickey teaches that the frame member is substantially rigid (col. 6 lines 22-35 of Ede).

Regarding claim 5, Hickey teaches that the floor comprises first and second flexible layers of different materials (i.e. barrier 35 and substrate 28) the substrate 28 comprising a flexible piezoelectric material (page 16 line 21), and wherein, in operation, the piezoelectric material underlying a target blister is configured to repeatedly flex generally upward and downward upon receipt of an electrical input (page 18 lines 3-8).

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Regarding claim 6, Hickey teaches that the floor second layer comprises the piezoelectric material (a piezoelectric polymer is disclosed on page 14 line 25) and is attached to a bottom of the floor first layer (i.e. 35), the floor second layer further comprising a predetermined conductive pattern (i.e. trace pattern 22u or 22b) disposed over a first primary surface (upper surface u or bottom surface b) and a conductive material (i.e. metal) disposed over at least a portion of an opposing second primary surface (upper surface 21u or bottom surface 21b).

Regarding claim 7, Hickey discloses that the conductive material on the second primary surface (i.e. 21u) of the second layer comprises a metalized coating disposed to cover substantially all of the second primary surface (page 20 lines 1-17).

Regarding claim 8, Hickey teaches in fig. 3 that the predetermined conductive pattern on the second layer comprises a plurality of spaced apart conductive regions (i.e. the region surrounding pad 25u as conductive region), each region sized and configured to substantially cover a surface area of a bottom portion of a respective blister underlying each gap space.

Regarding claim 9, Hickey teaches that the predetermined conductive pattern further comprises at least one signal trace (26u) extending away from each region.

Regarding claim 10, Hickey teaches that the signal trace (26u) for each blister travels toward a contact zone (i.e. contact pad 25u) on the first primary surface (21u) of the second layer (28) to allow selective electrical excitation of at least one target blister in operation.

Regarding claim 11, Hickey teaches from figs. 2 and 4 that the ceiling (45) and first layer (i.e. 35) of the floor have a circular shape when viewed from the top with respective substantially aligned center apertures (20o) that define a window to expose a portion of an upper surface of

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the second layer (page 17 lines 16-31 disclose that the opening defines a window for access to the electrical connections of the upper surface of the second layer).

Regarding claim 13, Hickey teaches from fig. 5C that neighboring pairs of blisters comprise a different dry powder held therein (page 22 lines 6-7).

Regarding claim 14, Hickey teaches from fig. 5C that neighboring pairs of blisters are positioned closer to each other than non-neighboring blisters, and wherein each blister of a pair of neighboring blisters includes a different dry powder held therein (page 22 lines 6-7).

Regarding claim 15, Hickey discloses that the neighboring blisters are sized and configured to, in operation and in position in an inhaler to release their dry powders substantially concurrently to a user upon inhalation (page 22 lines 1-3).

Regarding claim 17, the modified Hickey discloses that the frame member is a laminated structure (col. 6 lines 24 and 31 of Ede disclose that the carrier 10 as frame can be made of composites as laminated) having increased structural rigidity relative to the floor and/or ceiling (col. 7 line 43 of Ede discloses that the sheets i.e. 12 can be made from foil while col. 6 lines 21-30 of Ede disclose that the frame can be made of metal or ceramic and can have holes punched through it).

Regarding claim 18, the modified Hickey teaches in fig. 1 that the floor (14) and the ceiling (12) have substantially the same thickness and that the frame member is a unitary polymer structure having increased structural rigidity relative to the floor and ceiling (col. 6 lines 22-23 of Ede discloses that the frame can be a polymer and col. 7 line 43 of Ede discloses that the sheets i.e. 12 can be made from foil).

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Regarding claim 20, Hickey teaches in fig. 3A and 10A wherein the ceiling (the combination of barrier 35, pads 25u, 25b and substrate layer 28 as ceiling or only substrate 28 as ceiling) comprises a generally planar sealant layer (i.e. barrier 35 or substrate 28 as sealant layer) sealably attached to the blister to define a ceiling when the device is an upside-down orientation.

Regarding claim 21, Hickey teaches that the ceiling (28) comprises a piezoelectric polymer (page 19 lines 22-23).

Regarding claim 22, Hickey teaches that the ceiling (45) is a sealant polymer coating (page 6 line 22) and can thus be deduced to be moisture resistant. In addition page 15 lines 25-26 disclose moisture resistant barriers. However, Hickey does not specifically disclose that the ceiling comprises foil. Ede however teaches a ceiling with moisture resistant foil (col. 4 lines 1-5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the ceiling with polymer coating of Hickey with the moisture resistant foil as taught by Ede to provide increased sealing ability with the device and increased moisture resistance. It is noted that aluminum foil with polymer coatings are old and well known in the art.

Regarding claim 23, Hickey discloses that the second layer of the floor comprises a piezoelectric polymer (page 14 lines 25-26).

Regarding claims 24 and 72, Hickey teaches from figs. 3, 4, 7, and 8 that the combination of barrier 35, pads 25u, 25b and substrate layer 28 as floor or sealant layer 45 as floor, depending on the orientation of the device are both substantially planar and the modified Hickey discloses that opposing sidewalls of a respective gap space are inclined so that the sidewalls taper farther

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away from each other from a bottom to top portion thereof (col. 10 lines 28-37 of Ede disclose that the walls can be angled 3 degrees from 90 with a wider opening at the top) and that the thickness of the frame is at least 15 times greater than the floor or ceiling (Ede discloses in col. 8 line 60, col. 9 line 4, 56-58 that the frame could have a thickness of about 3mm-5mm. Since the lidding foils of the floor and ceiling are typically 0.2mm, the frame is at least 15 times thicker than the foil.

Regarding claim 26, Hickey teaches a power source (150); an input signal generating circuit (125) that is in communication with the power source and is configured to provide electrical input to selectively flex the floor of a target blister (page 25 lines 22-32); and a non transitory computer readable storage medium (page 25 lines 11-13) having computer readable program code (page 26 lines 9-12) that is in communication with the signal generating circuit and is configured to define at least one predetermined non-linear vibration input signal selected to represent *a priori* flow characteristic frequencies of the dry powder held in the blisters (page 26 lines 1-12).

Regarding claim 66, Hickey teaches from figs. 3, 4, 7, and 8 that the combination of barrier 35, pads 25u, 25b and substrate layer 28 as floor or sealant layer 45 as floor, depending on the orientation of the device are both substantially planar and the modified Hickey discloses that the frame member comprises a molded polymer (col. 6 lines 22-23 of Ede) with sidewalls that are about 2mm deep (col. 9 lines 56-57 of Ede).

Regarding claim 67, the modified Hickey teaches from fig. 1 of Ede that the frame member apertures are substantially circular when viewed from the top and bottom).

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Regarding claim 71, the modified Hickey discloses that the frame member gap spaces are about 2mm long (col. 9 line 14 discloses that the gaps can be about 2mm long along the vertical axis).

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hickey in view of Ede, as applied to claim 1 above, and further in view of Newell et al. (4,627,432).

Regarding claim 12, Hickey teaches in fig. 1 and page 18 lines 9-16 rotating the blister package but does not specifically disclose a rotatable gear having circumferentially spaced apart gear teeth, the gear extending through the open center and attached to the frame member so that the blister package rotates with the gear. However, Newell teaches in fig. 1 a rotatable gear (12) having circumferentially spaced apart gear teeth (the grooved notches around the gear as teeth), the gear being located in the open center (col. 2 lines 54-61) so as to be able to be proximate the window of the aligned center apertures and attached to the frame member (10) so that the blister package (8) rotates with the gear. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the rotary mechanism of Hickey with the centered gear mechanism as taught by Newell to provide a rotary means that won't interfere with the electrical traces and couplings and to securely hold the blister package during rotation.

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9. Claims 25, 68, and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickey in view of Ede, as applied to claim 1 above, and further in view of Casper (2007/0181124).

Regarding claims 25, 68, and 70, the modified Hickey discloses that the walls can be inclined with rounded end (col. 9 lines 56-58 of Ede) but does not specifically disclose that the walls can be coned shaped having substantially constant angles of inclination of between about 20-40 degrees from a bottom to a top portion thereof. However, Casper teaches in figs. 5b and 6b side walls of a blister that are coned shaped with an angle of inclination of approximately 40-45 degrees. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the sidewalls of the modified Hickey with the cone shaped angle of inclination as taught by Casper to facilitate dosage removal. In addition such a change would be considered a design choice, requires a mere change in shape of a component, and would function equally well. Hickey teaches the rest of the limitations as claimed. See the rejection of claim 66 above.

Response to Arguments

10. Applicant's arguments on page 9 directed to Snow as it relates to the newly added claim limitations have been considered. A new ground of rejection has been made in view of Ede.

11. Applicant's arguments filed 3/29/2011 have been fully considered but they are not persuasive.

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Regarding applicant's arguments on page 10 2nd full paragraph, applicant argues "if one were to modify Hickey with Ede, then the resulting dose package would include the frame and the insert cups holding the dry powder." Examiner respectfully disagrees. Examiner has only relied upon the teaching of the frame member and its thickness in Ede and is not combining Ede's entire blister package with that of Hickey. Instead, Examiner has noted that one of ordinary skill in the art upon seeing the frame thickness of Ede would be able to provide the blister pack of Hickey with the frame as taught by Ede to provide the advantage of allowing larger doses to be contained.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya M. Louis whose telephone number is (571)270-5337. The examiner can normally be reached on Monday-Friday, 8:30am-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LaToya M Louis/

Examiner, Art Unit 3771

7/28/2011

/Justine R Yu/

Supervisory Patent Examiner, Art Unit 3771